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10/509,931

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Armin Studer

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JONES DAY  
222 EAST 41ST STREET  
NEW YORK, NY 10017-6702

EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3738

MAIL DATE

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06/15/2007

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/509,931

Applicant(s)

STUDER, ARMIN

Examiner

Alvin J. Stewart

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-55 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/01/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: attachment

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner is unable to find the word "homogenous" in the original disclosure of the invention. Correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 38-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 discloses that the width of the member decreases from a first point located between the ends to the interior end. This is unclear, the Applicant's representative has only disclose two ends (exterior and interior) and how the width decreases between the ends (plural, interior and exterior) to the interior end. It is unclear, why the interior end is mentioned twice in claim 32.

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Regarding claim 38, the examiner is clear in how the first point is between the interior and exterior ends. However, it is not clear which direction the width of the member decreases.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-26 and 31, 33-46, 49-51 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Husson et al US Patent 5,919,235.

Husson et al discloses an intervertebral implant (S) comprising a longitudinal flexible body that can be wound in a spiral shape (see Figs. 3 and 2) with a first exterior end (5), a second interior end (1), a longitudinal axis and a cross section of the object which is orthogonal towards the central axis is reduced in size towards the second interior end.

Regarding independent claims, see attachment in order to see the Examiner's point of view. The Applicant's representative has to clearly point out where the interior and exterior ends start and where they ends. In the independent claims the Applicant's representative is disclosing that the flexible homogenous member has exterior and interior ends. The Applicant's representative should disclose the following in order to clarify the invention. For example, "the longitudinal flexible member discloses a distal exterior end and a distal interior end extending between the length of the longitudinal central axis of the prosthesis" so the Examiner cannot interpreted the interior and exterior lateral walls of the implant.

Regarding claims 21-23, see attachment.

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Regarding claim 26, see Figs. 1 and 2.

Regarding claims 33-34, see col. 5, lines 22-27.

Regarding claim 35, see Fig. 1.

Regarding claims 24 and 36, see Fig. 2A.

Regarding claims 31, 37 and 49, a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3 (CCPA 1976).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-30, 32, 47, 48, 52, 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husson et al US Patent 5,919,235.

Husson et al discloses the invention substantially as claimed. However, Husson et al does not disclose a gap having a width of no more than about 1.0 mm wide, a surface area between about 250 mm<sup>2</sup> and 750 mm<sup>2</sup> and the member made of hydrogel.

It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the width, the surface area and the material property of the Husson et al reference because Applicant has not disclosed that by having the gap width, surface area and the hydrogel material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the gap, the surface area and the material disclosed in the Husson et al reference because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Husson et al reference to obtain the invention as specified in claims 27-30.

Regarding claims 32 and 52, At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to add a recess with an injection point at the upper surface near the interior end of the implant because Applicant has not disclosed that by having a recess with an injection point provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with flat surface because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Husson et al reference to obtain the invention as specified in claims 32 and 52.

Regarding claims 54 and 55, At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to add indentations and have a cross section width smaller than the inner layers because Applicant has not disclosed that by having a cross section width smaller than the inner layers and an indentation provides an

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advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with above mentioned limitations because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify Husson et al reference to obtain the invention as specified in claims 54 and 55.

### ***Response to Arguments***

Applicant's arguments filed 04/20/07 have been fully considered but they are not persuasive.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3738

May 30, 2007



# Attachment.

U.S. Patent

Jul. 6, 1999

Sheet 1 of 4

5,919,235

Fig.1

